OCT 1 1 2002

MEVISYS
(주)메비시스

510(k) Summary of Safety and Effectiveness

K022692

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
July 25, 2002

Submitter's Information: 21 CFR 807.92(a)(1)
Mevisys, Co., Ltd.
Alumni Venture Hall, Room 5103
KAIST,
400 Gusongdong Yusonggu
Daejon 305-701
Korea

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	VoxelPlus™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K992654
Device Name	PLUG 'N VIEW 3D
Applicant	VOXAR LIMITED BONNINGTON BOND, 2 ANDERSON PL EDINBURGH, UK EH6 5 NP
Contact	ROB MACKEAN
Product Code	LLZ
Date Received	08/09/1999
Decision Date	11/05/1999

Device Description: 21 CFR 807 92(a)(4)
Mevisys VoxelPlus™ is a PC-based software application that imports medical images (i.e. CT, MRI modalities) in a DICOM format and provides various functions for rapid and easy review. It includes 3D volume rendering, various MPR, and many 2D analysis tools. The tools manage images, requests, patients, examination etc. over a high-speed network to allow information and images flow throughout a user facility.

Indications for Use: 21 CFR 807 92(a)(5)

The VoxelPlus™ is a software application for the for the display and 3D visualization of medical image data derived from various sources (i.e. CT scanners, MRI scanners). Images and data can be acquired, stored, communicated, processed, printed, rendered, and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is a software application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for VoxelPlus™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. VoxelPlus™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Mevisys Co., Ltd.
% Mr. Carl Alletto
1100 Lakeview Blvd.
DENTON TX 76208

Re: K022692
Trade/Device Name: VoxelPlus™ PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 27, 2002
Received: August 13, 2002

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MEViSYS
(주)메비시스

(Indications for Use Form)

510(k) Number: K022692

Device Name:
VoxelPlus™ by MEViSYS Co. Ltd.

Indications for Use:

The VoxelPlus™ is a software application for the for the display and 3D visualization of medical image data derived from various sources (i.e. CT scanners, MRI scanners). Images and data can be acquired, stored, communicated, processed, printed, rendered, and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Segroves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022692